

Appl. No. : 10/770,712
Filed : February 3, 2004

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AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for ~~determining etiology of~~ diagnosing an autistic spectrum disorder in a patient, comprising the steps of:

a) determining a level of at least one infectious agent derived antigen or antibody against an infectious agent derived antigen, at least one toxic chemical derived antigen or an antibody against a toxic chemical, and at least one dietary protein derived antigen or antibody against a dietary protein, in one or more samples from the patient;

b) comparing the level of antigens and/or antibodies determined in step a) with a normal level of the antigens and/or antibodies from control subjects, wherein

(i) normal level or lower than normal level of antigens and/or antibodies for the each of said antigens indicate ~~absence of an etiology~~ the presence of autistic spectrum disorder ~~from presence of said antigens~~; and

(ii) higher than normal level of antigens and/or antibodies for one or more of said antigens and/or antibodies ~~indicates a likelihood~~ the presence of the autistic spectrum disorder ~~being based on the presence of said antigens~~.

2. (Original) The method of claim 1, wherein higher than normal levels of antibodies to the infectious agent derived antigen indicates a likelihood of the autistic spectrum disorder being based on a vaccine or prior infection.

3. (Original) The method of claim 1, wherein the infectious agent derived antigen is selected from the group consisting of measles, mumps, rubella, diphtheria toxoid, pertussis, tetanus toxoid, hepatitis B, herpes type 6, and clostridium neurotoxin.

4. (Original) The method of claim 1, wherein the toxic chemical derived antigen is mercury or a mercury-based compound.

5. (Original) The method of claim 1, wherein the dietary protein derived antigen is selected from the group consisting of milk, casomorphin, wheat gluten/gliadin, gluteomorphin, corn, and soy.

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6. (Original) The method of claim 1, further comprising determining an antibody level of a self-tissue or peptide, wherein the self-tissue or peptide can bind to the infectious agent derived antigen, the toxic chemical derived antigen or the dietary protein derived antigen.

7. (Original) The method of claim 6, wherein the self-tissue or peptide is selected from the group consisting of tissue and cell antigens, receptors, mediators, enzymes, or neurotransmitters.

8. (Original) The method of claim 6, wherein the self-tissue antigen or peptide is selected from the group consisting of digestive enzyme, aminopeptidase, dipeptidyl peptidase IV, CD26, DPPI, CD13, CD69, transglutaminase, epithelial cells, brush border antigens and enzymes, colon tissue antigens, gastrin, gastrin inhibitory polypeptide, secretin, motilin, enkephelin, substance P, somatostatin, and serotonin.

9. (Original) The method of claim 6, wherein the self-tissue antigen or peptide is a neurotransmitter receptor or neurotransmitter.

10. (Original) The method of claim 9, wherein the self-tissue antigen or peptide is selected from the group consisting of serotonin receptor, serotonin, somatostatin, vasoactive intestinal peptide, prodynorphin, dynorphin, dipeptidylpeptidase IV, and complex dipeptidylpeptidase IV.

11. (Original) The method of claim 6, wherein the self-tissue antigen or peptide is selected from the group consisting of myelin basic protein, neurofilament, tubulin, cerebellar, glutamate receptor, ion channel, transaldolase, streptokinase, heat shock proteins, HSP60-90, exotoxin, endotoxins and wherein the dietary protein derived antigen is milk, milk casein, milk casomorphin, gliadin, gliadomorphins, milk butyrophilin, and wherein the infectious agent derived antigen is selected from the group consisting of streptococcus M protein and chlamydia pneumoniae.

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12. (Original) The method of claim 6, wherein the self-tissue antigen or peptide is selected from the group consisting of antinuclear antibody, fibrillarin, chromatin, immune complexes, and metallothionein, and wherein the toxic chemical derived antigen is mercury or a mercury-based compound.

13. (Original) The method of claim 1, wherein the autistic spectrum disorder is selected from the group consisting of autism, pervasive developmental disorder, and Asperger's Syndrome.

14. (Original) The method of claim 13, wherein the autistic spectrum disorder is autism.

15. (Original) The method of claim 1, wherein the normal level of antibodies is calculated by taking a mean of levels of antibodies in individuals without symptoms relating the autistic spectrum disorder.

16. (Original) The method of claim 1, wherein the higher than normal level of antibodies is higher than about two standard deviations of normal level of antibodies of a control group.

17. (Original) The method according to claim 1, wherein determining the level of antibodies in any or all of steps a) and b) is accomplished using an immunoassay.

18. (Original) The method according to claim 17, wherein the immunoassay is selected from the group consisting of ELISA, RAST, dot blot, Western blot, and ELISPOT.

19. (Original) The method according to claim 1, wherein the antibodies are selected from the group consisting of IgG, IgA, and IgM.

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20. (Currently amended) A method for ~~determining etiology of~~ diagnosing an autistic spectrum disorder in a patient, comprising the steps of:

a) determining a level of antibodies to a self-tissue or peptide selected from the group consisting of a digestive enzyme, aminopeptidase, dipeptidyl peptidase IV, CD26, DPPI, CD13, CD69, transglutaminase, epithelial cells, brush border antigens and enzymes, colon tissue antigens, gastrin, gastrin inhibitory polypeptide, secretin, motilin, enkephelin, substance P, somatostatin, serotonin receptor, serotonin, somatostatin, vasoactive intestinal peptide, prodynorphin, dynorphin, dipeptidylpeptidase IV, and complex dipeptidylpeptidase IV in one or more samples from the patient; and

b) comparing the level of antibodies determined in step a) with a normal level of the antibodies from control subjects, wherein

(i) normal level or lower than normal levels of antibodies indicate absence of ~~etiology of autistic spectrum disorder from presence of said antibodies~~ in said patient; and

(v) (ii) higher than normal level of the antibodies indicates a likelihood the presence of the autistic spectrum disorder ~~being based on the presence of said antibodies~~ in said patient.

21. (Canceled)

22. (Canceled).

23. (Canceled).

24. (Original) The method of claim 20, wherein the autistic spectrum disorder is selected from the group consisting of autism, pervasive developmental disorder, and Asperger's Syndrome.

25. (Original) The method of claim 24, wherein the autistic spectrum disorder is autism.

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26. (Original) The method of claim 20, wherein the normal level of antibodies is calculated by taking a mean of levels of antibodies in individuals without symptoms relating the autistic spectrum disorder.

27. (Original) The method of claim 20, wherein the higher than normal level of antibodies is higher than about two standard deviations of normal level of antibodies of a control group.

28. (Original) The method according to claim 20, wherein determining the level of antibodies in any or all of steps a) and b) is accomplished using an immunoassay.

29. (Original) The method according to claim 28, wherein the immunoassay is selected from the group consisting of ELISA, RAST, dot blot, Western blot, and ELISPOT.

30. (Original) The method according to claim 20, wherein the antibodies are selected from the group consisting of IgG, IgA, and IgM.